IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC., Defendant.	Case No. 1:22-cv-00061-TSK **JURY TRIAL DEMANDED**

PLAINTIFF'S REPLY IN SUPPORT OF
MOTION REQUESTING EXPEDITED STATUS CONFERENCE

Regeneron seeks an expedited status conference to position this case for trial next summer so that Regeneron may avail itself of statutory injunctive relief set forth in 35 U.S.C. § 271(e)(4)(D). Congress created that relief precisely for biosimilar patent cases like this one, and the availability of that relief is central to Regeneron's request for an expedited status conference. Mylan's opposition, however, says *not one word* about § 271(e)(4)(D). Mylan thus does not dispute that Regeneron is entitled to seek § 271(e)(4)(D) relief in this case, nor does it dispute that such relief requires a final court decision in advance of any approval of Mylan's biosimilar product. Mylan's tacit acknowledgement that a primary basis for relief in this case necessitates a rapid case schedule alone justifies an expedited status conference. Notably, while Mylan quibbles with Regeneron's proposed schedule, it does not dispute that an expedited status conference is warranted.

Mylan argues that a rapid case schedule would "delay[] patent certainty" (Opp. 3), but precisely the opposite is true. Regeneron's proposal provides certainty to *both parties* regarding the entitlement to relief under § 271(e)(4)(D). Because Regeneron seeks such relief only as to the twelve patents listed in its motion, a case schedule designed to try those patents in time for a

final appellate decision before approval of Mylan's biosimilar product will achieve complete certainty—for both Regeneron and Mylan—as to those twelve patents and to Regeneron's entire claim for § 271(e)(4)(D) injunctive relief. Mylan itself recognizes that an early trial date for all patents in the Complaint "is simply not feasible" (Opp. 2), and yet Mylan provides no alternative plan for achieving the "patent certainty" that it desires for any patent before its biosimilar is approved. Mylan's apparent strategy is to run out the proverbial clock on Regeneron's primary requested relief, rather than contesting Regeneron's entitlement to that relief on the merits.

An expedited status conference will enable the Court and the parties to fashion a plan for positioning this case for a prompt trial and for achieving certainty for both parties' benefit. Although the Court set several initial case deadlines after Regeneron filed this motion (*see* ECF 19), Regeneron respectfully requests that the Court schedule a status conference at its earliest possible convenience.

In the meantime, Regeneron is making every effort to prepare this case to be litigated swiftly: Regeneron already has contacted Mylan about scheduling the Court-ordered Initial Planning Meeting; Regeneron has transmitted to Mylan a draft Protective Order and draft discovery requests for review; and in response to Mylan's request for an "indication as to how many documents [Regeneron] intends on producing" (Opp. 7 n.2), Regeneron provides in this Reply an indication of the volume and contents of its initial document production, which Regeneron will deliver to Mylan immediately upon entry of a Protective Order.

Because the parties agree that the relief sought in this case requires a rapid case schedule, and because a rapid case schedule will provide both parties with certainty as to that requested relief, Regeneron respectfully requests that the Court schedule an expedited status conference at its earliest convenience.

I. REGENERON HAS A VIABLE CLAIM UNDER § 271(e)(4)(D)

Mylan cannot and does not contest that Regeneron has a viable claim under § 271(e)(4)(D). Instead, Mylan focuses its arguments on other statutory provisions and forms of relief, none of which is a substitute for § 271(e)(4)(D).

Mylan first attempts to deny the need for an expedited schedule by rewriting the biosimilar patent statute. Mylan asserts, without citation, that "Congress created a patent resolution scheme that is wholly separate from FDA's regulatory review." Opp. at 10. But that is facially untrue—§ 271(e)(4)(D), by its express terms, requires particular relief in circumstances where "the [biosimilar] product *has not yet been approved*" by FDA. The connection between "the patent resolution scheme" and "FDA's regulatory review" could not be plainer. And it is the express connection between the two that necessitates an expedited status conference to discuss case scheduling and enter a schedule that facilitates the relief Congress provided, rather than negating it.

Next, Mylan contends that Regeneron can seek an injunction through other means provided it "satisf[ies] the requirements for such extraordinary relief, just as any litigant can do." ECF 26 ("Opp.") at 2-3. But the general ability of a litigant to seek an injunction under the principles of equity is no substitute for the specific, mandatory statutory relief provided by § 271(e)(4)(D). Equitable injunctive relief involves consideration of the four traditional equitable factors. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006) ("[1] [plaintiff] has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction"). By contrast, the injunctive relief Congress enacted in § 271(e)(4)(D) requires that a court "*shall order a permanent*

injunction prohibiting any infringement of the patent" by the biosimilar while the patent is in force and before the biosimilar has been approved. An injunction under § 271(e)(4)(D) is thus mandatory, not "extraordinary," and it is specifically created for an innovator biopharmaceutical company whose product a biosimilar company seeks to copy.

Similarly, Mylan wrongly suggests that "the procedure contemplated by the BPCIA" is a motion for preliminary injunction. Opp. at 10. But a preliminary injunction, unlike relief under § 271(e)(4)(D), is subject to similar equitable considerations as a permanent injunction. *See Winter v. Nat. Res. Def. Council*, 555 U.S. 7 (2008). Relatedly, Mylan misreads the BPCIA, which stages preliminary injunction proceedings later in litigation. A preliminary injunction is a remedy available *after* the biosimilar provides its notice of commercial marketing, which has not yet occurred here. 42 U.S.C. § 262(*l*)(8)(B); *see* Opp. at 6 ("Mylan has not yet provided its advance 180-day notice of commercial marketing."). That notice initiates the "second phase" of BPCIA litigation, which includes the possibility for a preliminary injunction. *AbbVie Inc. v. Alvotech hf.*, 2022 WL 225881, at *2 (N.D. Ill. Jan. 26, 2022). Here, however, the parties are in the "first phase," "i.e., before the biosimilar goes to market" and before the biosimilar has been approved. *Id.* A preliminary injunction is thus not a substitute for the specific, congressionally mandated relief provided under § 271(e)(4)(D).

Mylan cites several prior biosimilar cases but elides a crucial distinction from this case. In those cases (Opp. at 11 n.4), FDA approval of the biosimilar product *preceded* the district court's decision in related patent litigation, because the regulatory exclusivity for each innovator product had already expired by the time the lawsuit was filed.[1] In those cases, there was no

[1] The BPCIA was enacted as part of the Affordable Care Act in 2010. The products at issue in the first wave of BPCIA cases had been approved many years earlier—most in the 20th century—so that their regulatory exclusivities (and attendant proscriptions against FDA approval

possible path to a "final court decision"—and thus no possibility of any § 271(e)(4)(D) relief—prior to FDA approval of the biosimilar.[2] In the present case, by contrast, Regeneron expects its regulatory exclusivity for Eylea to remain in force through May 2024, thereby permitting the final appellate decision to predate FDA approval, as Congress envisioned in § 271(e)(4)(D). *See* Mot. at 5. In fact, this is the first biosimilar patent case that will proceed while the innovator product's regulatory exclusivity remains in place. That timing makes Regeneron's claim under § 271(e)(4)(D) viable, provided that this case proceeds expeditiously to trial. And Mylan's cases provide no support for its argument that Regeneron "would not lose any substantive rights under" a less expedited schedule. Opp. at 10 & n.4. On the contrary, there can be no dispute that Mylan's proposed schedule necessarily would deprive Regeneron of statutory relief—that is the animating principle behind Mylan's proposal.

Mylan also suggests, without support, that the biosimilar applicant enjoys "[t]he statutory right to control the timing and scope of litigation under the BPCIA." Opp. at 13. A biosimilar applicant does control the patent dance exchanges—as Mylan did here by forcing the parties to litigate twenty-four patents in this action, Mot. at 3—and when to provide its notice of commercial marketing. *See Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1666 (2017).[3] But there is no statutory authority permitting a biosimilar company to extend the litigation and expunge, without prevailing on the merits, the innovator's right to relief under § 271(e)(4)(D).

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of a biosimilar) had expired by the time biosimilar litigation began. In this case, by contrast, the litigation is occurring while the regulatory exclusivity remains in place.

[2] As Mylan notes, unlike in the Hatch-Waxman context, the filing of an infringement suit does not stay FDA approval of a biosimilar. Opp. at 9.

[3] Mylan observes that the biosimilar cedes control under the BPCIA when it fails to comply with the patent dance, *Sandoz*, 137 S. Ct. at 1666, but that is irrelevant here. There is no dispute that both parties complied with the patent dance.

Lacking a response to the urgency required by Regeneron's § 271(e)(4)(D) claim, Mylan also accuses Regeneron of other supposed "true motivation[s]" to advance this case quickly to trial. Opp. at 8. None is accurate.

First, Mylan suggests that Regeneron seeks to deprive Mylan of discovery, *id.*, but Mylan admits that Regeneron has already provided "hundreds of pages of detailed contentions" providing Mylan notice of Regeneron's claims. Additionally, Regeneron is also prepared to make a substantial document production *immediately* upon entry of a protective order, so that fact discovery may begin imminently. In response to the request in Mylan's opposition for "an indication as to how many documents [Regeneron] intends on producing," Regeneron provides the following information in an effort to further the parties' discovery preparedness. Within 48 hours after entry of a protective order, Regeneron intends to produce:

- 65 lab notebooks pertaining to relevant research and development.
- Over 3,000 internal, technical documents relating to research and development on aflibercept formulations.
- Custodial email data from 21 inventors of the patents-in-suit, including each inventor from Regeneron's proposed twelve patents for whom email data are available.
- Modules 1 through 4 of the Biologics License Application for Eylea, along with relevant portions of Module 5.
- The certified patents, file histories, and assignment histories for each of the 24 patents asserted in the complaint.
- Regeneron's annual reports from 2008 through 2021, and Regeneron's Form 10-K for fiscal years 1999 through 2021.

- Employment agreements for multiple inventors of the patents-in-suit.

Second, Mylan suggests that a fast trial date will increase the likelihood that the Patent Trial and Appeal Board ("PTAB") will exercise its discretion to deny two of Mylan's *inter partes* review challenges. Opp. at 8-9. However, Regeneron does not even seek to litigate one of these two patents in the first-stage litigation (*see* Mot. at 6). Regardless, Mylan chose to delay strategically the filing of its two recent petitions—instead of filing them at the same time as its earlier-filed petitions last May, it filed them only last month—and thus any alleged prejudice is of Mylan's own making. Mylan's provisional concern about one factor (among many) that might affect one *inter partes* review is hardly a basis to delay the trial.[4]

Third, Mylan asserts that the second-stage patents are tantamount to a "sword of Damocles" over Mylan while the first-stage patents are litigated. Opp. at 8. But as Regeneron explained (*see* Mot. at 6), severing and staying claims on certain patents is hardly unprecedented in complex patent ligation, and is particularly appropriate in the biosimilar context where the statute contemplates litigating a "first phase" with a narrower set of patents "before the biosimilar goes to market." *AbbVie*, 2022 WL 225881, at *2. That is precisely what Regeneron proposes here. More fundamentally, under Mylan's proposed schedule, litigation through appeal as to *all 24 patents* would not be completed before FDA approval, making whatever sword of Damocles Mylan conjures more menacing, not less.

[4] In view of the PTAB's recent guidance, a district court trial schedule is only one among several factors relevant to the PTAB's decision to institute. Katherine K. Vidal Memorandum, *Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation*, United States Patent and Trademark Office (June 21, 2022), https://www.uspto.gov/about-us/news-updates/director-vidal-provides-clarity-patent-trial-and-appeal-board-practice.

II. RELIEF UNDER § 271(e)(4)(D) IS FEASIBLE

Mylan asserts that a June 2023 trial is not feasible, Opp. at 6, largely by ignoring Regeneron's proposal to narrow this case and begin discovery quickly and the requirement in Rule 40 to prioritize actions involving federal statutory rights at risk of being mooted through delay. Mot. at 3-4, 6. The parties are apparently in agreement that keeping all twenty-four patents in the case is incompatible with a fast schedule. Opp. at 6-7; Mot. at 6. Where the parties differ is whether an expedited schedule could comport with the discovery necessary in this case. *Id.* Regeneron is committed and able to begin fact discovery immediately upon agreement of a protective order (Mylan already has Regeneron's proposed Order), including by producing within 48 hours of an Order the substantial document production outlined above. Likewise, Regeneron has contacted Mylan to schedule a Rule 26(f) meeting and has provided notice of the discovery Regeneron seeks from Mylan. A fast schedule will not deprive Mylan (or Regeneron) of reasonable discovery, and Regeneron intends to work cooperatively with Mylan to achieve a fast schedule while treating both parties fairly. While Mylan asserts that Regeneron's proposal fails to contemplate the "full scope of the many factual and legal issues," the ones listed by Mylan, such as "whether the claims of the asserted patents are invalid" and "the scope and construction of the claims" are typical issues in patent litigation and do not foreclose a fast schedule. Opp. at 7. Likewise, Regeneron obviously does not seek to assert the "566 potential claims at issue" among twenty-four patents at trial, but rather seeks to limit the number of patents now (Mot. at 6) and further narrow claims substantially as the case progresses.

Regeneron appreciates Mylan's offer to "make all reasonable efforts to work with Regeneron to prioritize a subset of patents for trial" and to discuss proposals to streamline the issues for the Court. Opp. at 14. Regeneron will do likewise, including to discuss proposals so that "Mylan receives certainty."

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CERTIFICATE OF SERVICE

I hereby certify that on August 23, 2022, I electronically filed the foregoing with the Clerk of the Court by using the Court's CM/ECF system. Counsel of record for all parties will be served by the Court's CM/ECF system.

/s/ Steven R. Ruby
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